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JUL 18 2002

510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's name:	TheraLight, Inc.
Submitter's Address:	2794 Loker Avenue West, Suite 105 Carlsbad, CA 92008-6616
Telephone:	(760) 930-8000
Contact:	Raymond A. Hartman
Date Prepared:	June 26, 2002
Device Trade Name:	UV120-2 UVA / UVB Phototherapy System
Device Common Name:	Targeted UVA / UVB Phototherapy System
Device Classification Name:	Ultraviolet lamp for dermatologic / skin disorders (ref. 21 CFR 878.4630)
Predicate Devices:	Lumenis, Ltd. BClear UVB Phototherapy System K020591 National Biological Corporation HOUVA II UVA Phototherapy System K885025 National Biological Corporation HOUVA II UVB Phototherapy System K885026

Device Description:

The TheraLight UV120-2 UVA / UVB Phototherapy System is a microprocessor-controlled, high-intensity ultraviolet light source. The desired dose of UVA or UVB light is selected using controls on the System front panel. The System provides "targeted" phototherapy, whereby the specified dose of UVA or UVB light is delivered via a flexible Lightguide and Handpiece. The System delivers a homogenous UV light dose to a localized ¾" square patch of skin without exposure to neighboring, healthy tissues.

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Intended Use:

The TheraLight UV120-2 UVA / UVB Phototherapy System is intended for use in PUVA photochemistry and UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis.

Substantial Equivalence:

The TheraLight UV120-2 UVA / UVB Phototherapy System emits UVA within a spectral band of 330-380nm, which is the same as that for the predicate HOUVA II UVA device (K885025). The TheraLight System and each of the cited predicate devices emit UVB within a spectral band of 290-330nm, which has been shown to be safe and effective in the treatment of the indicated skin diseases.

The major difference between the TheraLight device and the cited predicate devices is that the TheraLight device will emit either UVA or UVB. The user selects which spectra will be emitted using a switch on the device front panel. However, TheraLight believes that this difference is an added convenience, and does not raise new questions of safety or effectiveness.

Performance Data:

With regard to UVA light emissions, the TheraLight System is the first device to emit light via a small (3/4" square) Handpiece aperture. The predicate device was designed to provide whole body (or limb) exposure. The TheraLight, Inc. design allows for the treatment of lesional skin without exposure to healthy, neighboring tissues.

Performance data were submitted as part of the 510(k) to confirm that the spectral output from the TheraLight System is between 330-380nm for UVA, and between 290-330nm for UVB, which is similar to spectra emitted by predicate devices.

With regard to UVB light emission, the performance specifications for the TheraLight UV120-2 UVA / UVB Phototherapy System are the same as, or very similar to, those claimed by predicate devices.

Conclusion:

On the basis of the information provided in this Summary, TheraLight, Inc. believes the UV120-2 UVA / UVB Phototherapy System is substantially equivalent to legally commercialized predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2002

TheraLight, Inc.
c/o Mrs. Elizabeth Drew
Medical Device Services
Underwriters Laboratories, Inc.
1655 Scott Boulevard
Santa Clara, CA 95050-4169

Re: K022165
Trade/Device Name: TheraLight UV120-2 UVA/UVB Phototherapy System
Regulation Number: 878.4630
Regulation Name: Ultraviolet lamp for dermatological disorders
Regulatory Class: II
Product Code: FTC
Dated: June 17, 2002
Received: July 3, 2002

Dear Mrs. Drew:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022165

Device Name: TheraLight UV120-2 UVA/UVB Phototherapy System

Indications for Use:

The TheraLight UV120-2 UVA / UVB Phototherapy System is indicated for use in PUVA photochemistry and UVB phototherapy for the treatment of psoriasis, vitiligo, atopic dermatitis (eczema), and seborrheic dermatitis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022165

(Optional Format 3-10-98